



Docket No. PRD 2019

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Carruthers et al.

Serial No. : 10/734,800

Art Unit:

Filed : December 12, 2003

Examiner:

For : SUBSTITUTED 4-PHENYL-[1,3]-DIOXANES

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

March 25, 2004

(Date of Deposit)

John W. Harbour

(Name of applicant, assignee, or Registered Representative)

(Signature)

March 25, 2004

(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a) (2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the

national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

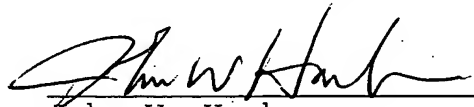
☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

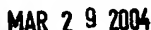
Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/PRD2019/JWH. This form is submitted in triplicate.

Respectfully submitted,



John W. Harbour
Reg. No. 31,365
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2169
DATED: March 25, 2004



Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

(use as many sheets as necessary)

Sheet 1 of 2

<i>Application Number</i>	10/734,800
<i>Filing Date</i>	December 12, 2003
<i>First Named Inventor</i>	Carruthers
<i>Group Art Unit</i>	
<i>Examiner Name</i>	
<i>Attorney Docket Number</i>	PRD 2019

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

Application Number	10/734,800
Filing Date	December 12, 2003
First Named Inventor	Carruthers
Group Art Unit	
Examiner Name	
Attorney Docket Number	PRD 2019

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		ALO, B.I. et al. Sequential Directed Ortho Metalation-Boronic Acid Cross Coupling Reactions. A General Regiospecific Route to Oxygenated Dibenzo[b,d]pyran-6-ones Related to Ellagic Acid. J. Org. Chem. 1991, 56:3763-3768.	
		AMMOUN, S. et al. Distinct Recognition of OX1 and OX2 Receptors by Orexin Peptides. J. Pharmacol. Exp. Ther. 2003, 305(2):507-514.	
		BLANCO, M. et al. Cellular Localization of Orexin Receptors in Human Pituitary. J. Clin. Endocrinol. Metab. 2001, 86(4):1616-1619.	
		CHEMELLI, R.M. et al. Narcolepsy in Orexin Knockout Mice: Molecular Genetics and Sleep Regulation. Cell 1999, 98(4):437-451.	
		CHEN, C.-T. et al. Pressor Effects of Orexins Injected Intracisternally and to Rostral Ventrolateral Medulla of Anesthetized Rats. Am. J. Physiol. 2000, 278(3):R692-R697.	
		DROUOT, X. et al. Low Levels of Ventricular CSF Orexin/Hypocretin in Advanced PD. Neurology 2003, 61(4):540-543.	
		FULTS, D. et al. Establishment and Characterization of a Human Primitive Neuroectodermal Tumor Cell Line from the Cerebral Hemisphere. J. Neuropathol. Exp. Neurol. 1992, 51(3):272-280.	
		HARA, J. Genetic Ablation of Orexin Neurons in Mice Results in Narcolepsy, Hypophagia, and Obesity. Neuron 2001, 30(2):345-354.	
		KIRCHGESSNER, A.L. and M.-T. LIU. Orexin Synthesis and Response in the Gut. Neuron 1999, 24(4):941-951.	
		LARSSON, K.P. et al. The STC-1 Cells Express Functional Orexin-A Receptors Coupled to CCK Release. Biochem. Biophys. Res. Commun. 2003, 309(1):209-216.	
		LIN, L. et al. The Sleep Disorder Canine Narcolepsy Is Caused by a Mutation in the Hypocretin (Orexin) 2 Receptor Gene. Cell 1999, 98(3):365-376.	
		LUBKIN, M. and A. STRICKER-KRONGRAD. Independent Feeding and Metabolic Actions of Orexins in Mice. Biochem. Biophys. Res. Commun. 1998, 253(2):241-245.	
		MIGNOT, E. et al. Complex HLA-DR and -DQ Interactions Confer Risk of Narcolepsy-Cataplexy in Three Ethnic Groups. Am. J. Hum. Genet. 2001, 68(3):686-699.	
		MIGNOT, E. and E. THORSBY. Narcolepsy and the HLA System. N. Engl. J. Med. 2001, 344(9):692.	
		MIYURA, N. and A. SUZUKI. Palladium-Catalyzed Cross-Coupling Reactions of Organoboron Compounds. Chem. Rev. 1995, 95:2457-2483.	
		NAKAMURA, T. et al. Orexin-Induced Hyperlocomotion and Stereotypy Are Mediated by the Dopaminergic System. Brain Res. 2000, 873(1):181-187.	
		NORDIN, I.C. and J.A. THOMAS. An Improved Synthesis of (4S,5S)-2,2-Dimethyl-4-phenyl-1,3-dioxan-4-amine. Tetrahedron Lett. 1984, 25(50):5723-5724.	
		PEYRON, C. et al. Neurons Containing Hypocretin (Orexin) Project to Multiple Neuronal Systems. J. Neurosci. 1998, 18(23):9996-10015.	
		PEYRON, C. et al. A Mutation in a Case of Early Onset Narcolepsy and a Generalized Absence of Hypocretin Peptides in Human Narcoleptic Brains. Nat. Med. 2000, 6(9):991-997.	
		PIPER, D.C. et al. The Novel Brain Neuropeptide, Orexin-A, Modulates the Sleep-Wake Cycle of Rats. Eur. J. Neurosci. 2000, 12(2):726-733.	
		SAKURAI, T. et al. Orexin and Orexin Receptors: A Family of Hypothalamic and G Protein-Coupled Receptors that Regulate Feeding Behavior. Cell 1998, 92(4):573-585.	
		SAMSON, W.K. et al. Cardiovascular Regulatory Actions of the Hypocretins in Brain. Brain Res. 1999, 831(1-2):248-253.	
		SHIRASAKA, T. et al. Sympathetic and Cardiovascular Actions of Orexins in Conscious Rats. Am. J. Physiol. 1999, 277(6, Pt.2):R1780-R1785.	
		TAKAHASHI, N. et al. Stimulation of Gastric Acid Secretion by Centrally Administered Orexin-A in Conscious Rats. Biochem. Biophys. Res. Commun. 1999, 254(3):623-627.	
		VAN DEN POL, A.N. Hypothalamic Hypocretin (Orexin): Robust Innervation of the Spinal Cord. J. Neurosci. 1999, 19(8):3171-3182.	
		WILLIE, J.T. et al. Distinct Narcolepsy Syndromes in Orexin Receptor-2 and Orexin Null Mice: Molecular Genetic Dissection of Non-REM and REM Sleep Regulatory Processes. Neuron 2003, 38(5):715-730.	
		YAMANAKA, A. et al. Orexins Activate Histaminergic Neurons via the Orexin 2 Receptor. Biochem. Biophys. Res. Commun. 2002, 290(4):1237-1245.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.